

§Appl. No. 09/890,654  
Amdt. dated August 10, 2005  
Reply to Office Action February 10, 2005

**In the Drawings:**

Attached at the end of this response is a literal translation of Fig. 1 which was filed in the PCT application and which could not be located by the Examiner.

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### **REMARKS**

#### **Rejection under §112, first paragraph**

An issue of new matter may arise when an amendment to a claim is not described in the application as filed, i.e., that the claim does not have an adequate written description. See, e.g., M.P.E.P. §706.03(o). To determine whether there is compliance with the written description requirement, the question must be answered whether “the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). See, also *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111. The test for sufficiency of support is whether the disclosure “reasonably conveys to the artisan that the inventor had *possession* at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). (Emphasis added.) See, M.P.E.P. §2163.02.

The specification clearly describes possession of the concept of standard curve and its inclusion in a kit. This was explained in detail on Pages 6-7 of the Response filed November 29, 2004. For example, the last sentence on Page 10 of the specification indicates that an unknown can be determined using the standard. The cited references were not to “demonstrate the possession of a concept after the fact,” but were to establish that the skilled worker would have recognized that the inventors had possession, at the time the application was filed, of a kit comprising a standard curve. Reagents kits commonly are sold with standard curves. Thus, a skilled worker would have expected a reagent kit to have a standard curve as a component of it. Upon reading the detailed disclosure in the application on standard curves (e.g., Page 3, lines 17-20; Page 4, lines 5-8; Page 9, lines 4-7; Page 10, lines 10-15; Fig. 1), the skilled would have recognized that a standard curve could be part of the kit, as well. A recent Board case (*Ex parte Eggleston*, B.P.A.I. 2005; not precedent) reaffirmed the principle that an “explicit” disclosure of

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claim terms is not required under 35 U.S.C. §112, first paragraph. "An invention claimed need not be described *ipsis verbis* in the specification in order to satisfy the disclosure requirements."

### **Rejections under §102**

Han et al. do not describe a standard curve. The standard curve is relevant for patentability purposes. In *In re Gulack*, the P.T.O. had rejected application claims, alleging that the printed matter did not confer patentability to an item that was otherwise well known in the prior art. The federal court reversed, finding that the numbers printed on the claimed band had a functional relationship to the band, itself. Similarly, the claimed standard curve is functionally related to the other components in the kit since it facilitates the determination of concentrations which is a purpose of the assay. Thus, the printed matter rejection is not appropriate.

Moreover, Han et al. do not disclose a kit where the coagulation-inhibiting substance is a fibrin polymerization inhibiting substance, such as a Gly-Pro-Arg-Pro-tetrapeptide. Compare, e.g., Claims 20-23. See, also, Specification, Page 5, lines 30-37.

### **Rejection under §103**

Applicant respectfully traverses the rejection. U.S. Pat. No. 5,702,912 (the '912 Patent) and Houbouyan et al. have been relied upon for their disclosure of a chromogenic substrate, and allegedly for teaching equivalence between chromogenic detection and clotting assays. However, neither the '912 Patent nor Houbouyan et al. disclose meizothrombin or meizothrombin-des-fragment 1 nor their activity on a chromogenic substrate. Thus, the combination of these references with U.S. Pat. No. 5,547,850 would have not led to the claimed invention. In order to establish obviousness, there must be motivation combined with an expectation of success. Neither the '912 Patent nor Houbouyan et al. provide the requisite motivation with an expectation of success, especially because they do not describe the activity of meizothrombin or

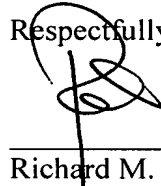
§Appl. No. 09/890,654  
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meizothrombin-des-fragment 1 on a chromogenic substrate. Consequently, the rejection should be withdrawn.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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